

Quality Assurance Manual



INDIANA STATE POLICE LABORATORY QUALITY ASSURANCE MANUAL

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1. Scope

This Quality Assurance Manual (QAM) contains or references the policies and procedures of the Indiana State Police Regional Laboratory System (Laboratory) quality management system to ensure technical competence and valid forensic examination results. The QAM facilitates meeting the American Society of Crime Laboratory Directors/Laboratory Accreditation Board-*International* (ASCLD/LAB-I®) Accreditation Program requirements.

ASCLD/LAB is an accrediting body for forensic science laboratories. The ASCLD/LAB-I program requirements are based on the International Organization for Standardization (ISO)/International Electrotechnical Commission (IEC) International Standard 17025 General Requirements for the Competence of Testing and Calibration Laboratories® (ISO 17025) and the ASCLD/LAB-*International* Supplemental Requirements for the Accreditation of Forensic Science Testing Laboratories®. The numbering of sections 4 and 5 of this QAM correspond to these standard documents.

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2. LABORATORY HISTORY

The Indiana State Police Laboratory was established in 1936 as the Department became aware that its proficiency in investigating criminal cases was dependent upon professional collection and analysis of technical evidence. It was a forensic service designed to benefit all criminal justice agencies within the state and continues to this day to assist various units of government, towns, counties, cities, military police and federal agencies.

The Department has long been aware that criminal or crash investigation is best augmented by laboratory analysis, exposing as it does details obscure or deliberately concealed. Today every police officer in the State is charged with the proper and meticulous collection of evidence, its preservation and transportation to a laboratory in a manner conforming to the rules of evidence.

It is axiomatic in law enforcement work that there are no perfect crimes, only imperfect investigations. The Indiana State Police Laboratory has been a part of the State's investigative teams since its inception, assisting investigators through crime scene processing and the analysis of physical evidence.

The system has grown from a small room in the Capitol basement to a complete and highly sophisticated system of four strategically placed facilities. Prior to 1977 all forensic examinations had to be performed at the Indianapolis facility, but in that year the Department began to extend its service by establishing the first "area laboratory" at Lowell, in northern Indiana. Now there are area laboratories at Fort Wayne and Evansville as well. The present system employs more than 170 police and civilian personnel, all trained in the various phases of identification and examination.

On June 1, 1991, the Laboratory Division achieved accreditation from the American Society of Crime Laboratory Directors/Laboratory Accreditation Board (ASCLD/LAB®). The Laboratory's continuing participation in the accreditation process demonstrates the Division's commitment and adherence to nationally recognized quality related standards and procedures.

On September 17, 2012, the four regional laboratories of the Indiana State Police Department attained ISO 17025 accreditation under the ASCLD/LAB-International program.

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3. Terms and Definitions

ASCLD/LAB-International® – An accreditation program of the American Society of Crime Laboratory Directors/Laboratory Accreditation Board (ASCLD/LAB®) in which any crime laboratory may participate to demonstrate that its management, technical operations and overall quality management system meet ISO 17025 General Requirements for the Competence of Testing and Calibration Laboratories and ASCLD/LAB-International® Supplemental requirements.

Accreditation – A process by which an authoritative body, such as ASCLD/LAB®, gives formal recognition that an entity is competent to carry out specific tests.

Administrative Records – Records, electronic or hardcopy, such as case related conversations, evidence receipts, Certificates of Analysis, chain of custody records, description of evidence packaging and seals, incident reports, service requests (Request for Laboratory Examination form), correspondence received/sent, subpoena, and other pertinent information.

Administrative Error – A clerical error such as a typographical error in a report or notes.

Administrative Review – Review of case records for consistency with laboratory policy and for editorial correctness.

Amended Certificate of Analysis – An official laboratory Certificate of Analysis with the appropriate correction when a substantive error is discovered in the original report.

Analytical/Interpretative Error – An error in the examination process that produces an incorrect result or conclusion.

Analyst (Examiner) – An individual who conducts the analysis of forensic casework samples.

Approved Test Provider – A proficiency test provider which has complied with the test manufacturing guidelines established and approved by the ASCLD/LAB® Proficiency Review Committees.

Association – A relationship which is concluded to exist between individuals and/or objects based upon an examination or analysis.

Audit – A systematic, independent, documented process for obtaining records, statements of fact or other relevant information and assessing them objectively to determine the extent to which specified requirements are fulfilled.

Case Records – Administrative and examination records, both electronic and hardcopy, generated or received by the Laboratory pertaining to a particular case.

Category of Testing (Sub-Discipline) – A specific type of analysis within an accredited discipline of forensic science.

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Certificate of Analysis – The official laboratory report that communicates the results, opinions and interpretations made during the analysis of evidence samples.

Certified Reference Material – Reference material accompanied by a certificate, one or more of whose property values are certified by a procedure, which establishes its traceability to an accurate realization of the units in which the property values are expressed, and for which each certified value is accompanied by an uncertainty at a stated level of confidence.

Chain-of-Custody – A process that documents all transfers of evidence over which the Laboratory has control.

Comparative Examination – Physical and/or chemical testing performed on two or more items for the purpose of determining any association between the items.

Competency Test – A test used to evaluate an individual's knowledge and ability to conduct examinations in a forensic discipline or category of testing prior to that person performing independent casework.

Competent – Possessing the requisite knowledge, skills and abilities to perform a job.

Contract – An agreement between the Laboratory and the customer to provide forensic testing services.

Control – A sample analyzed in parallel with test samples that is designed to demonstrate that a procedure worked correctly.

Controlled Document – A document that is issued and distributed in a traceable manner.

Corrective Action – A Laboratory response to eliminate or reduce the likelihood of recurrent non-conforming work or unauthorized departures from established policies and procedures.

Customer – A person or organization which requests the testing services of the Laboratory.

Deviation – An authorized variance from a documented policy, practice, or procedure. A deviation can be major or minor depending on the circumstances.

Discipline – A major area of casework for which a laboratory may seek accreditation.

Document Control – The process of ensuring that controlled documents prescribing quality-affecting activities or specifying quality requirements, including revisions, are reviewed for adequacy, approved for release by authorized personnel, and distributed for use to the personnel performing the prescribed activities.

Environmental Conditions – Any characteristic of the facilities that could reasonably be expected to impact the quality of the Laboratory's work product.

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Evidence – An item submitted for examination(s).

Examination – An analysis of an item or comparison of items.

Examination Records – The documentation, whether hardcopy or electronic, of procedures followed, tests conducted, standards and controls used, diagrams, printouts, photographs, observations and results of testing and examination.

External Proficiency Test – A test prepared and provided by a source external to the Indiana State Police Department.

Facilitation – The Laboratory makes arrangement for evidence to be sent to another laboratory for testing it does not perform. (Facilitation is not considered subcontracting of tests.)

Individual Characteristic Database – A collection of known samples, in computerized, searchable form, of features associated with an object or person uniquely or with a high degree of probability.

Individual Characteristic Database Sample – A specimen of known origin from which individual characteristic information originates (e.g., reference blood or biological specimens, fingerprints of known individuals, electronic fingerprint records, and test fired ammunition).

Internal Proficiency Test – A proficiency test administered and reported within the Laboratory.

Laboratory Case Number – A laboratory generated and unique identifier assigned to items of evidence submitted for examination.

Laboratory Manager – A Forensic Scientist E7 who has administrative management oversight responsibility for a regional laboratory within the Laboratory system.

Laboratory System Director – The Laboratory Division Commander.

Management System – The organizational structure, responsibilities, procedures, processes, and resources for implementing quality management.

Measurement Uncertainty – A parameter associated with the result of a measurement that characterizes the dispersion of the values that could reasonably be attributed to the measured quantity. Also known as uncertainty of measurement.

NIST – National Institute of Standards and Technology.

Open Proficiency Test – A proficiency test known to the participant as such.

Performance Check – Verification that equipment, instrument, or process is working as expected. Analysis of a control may be used as a performance check.

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Policy – A directive that embraces the general goals and acceptable practices of the Laboratory.

Preventive Action – A Laboratory action put into effect to reduce the likelihood of non-conformities in the technical operation as well as in the management system.

Proficiency Test – A test used to evaluate the continuing capability and performance of an analyst and the performance of the Laboratory.

Proper Seal – A seal that prevents loss, cross-transfer, or contamination while ensuring that accessing the evidence will result in obvious damage or alteration to the seal.

Qualified – A term used to identify personnel who successfully complete a unit's training program, pass a competency test and participate in the Laboratory's proficiency testing program.

Quality Assurance – Those planned or systematic actions necessary to provide sufficient confidence that the Laboratory's product or service will satisfy given requirements for quality.

Quality Assurance Manager – The Director of Forensic Analysis.

Quality Control – Activities used to monitor the quality of analytical data and to ensure that it satisfies specified criteria.

Quality Records – Records pertaining to the quality system such as audit reports, corrective actions reports, proficiency test logs, and testimony evaluations.

Quality System – The organizational structure, responsibilities, procedures, processes, and resources for implementing quality management.

Reagent – A substance used because of its known chemical or biological activity.

Record – A document that provides evidence of a condition, work performed, activities conducted, and/or quality for archival purposes.

Record of Dissemination – A process of documenting the release of information to a criminal justice agency with a need to know.

Re-examination Certificate of Analysis – Certificates of Analysis for cases which were reanalyzed.

Reference Collection – Data and items/reference materials which are maintained for identification, comparison or interpretation purposes.

Reference Material – A traceable material or substance having known properties. Reference materials may be used for the identification of unknown substances, performance checks of instruments, or assessments of a measurement method.

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Reference Standards – Standards from which measurements are made in order to confirm the required accuracy (example: NIST traceable weight set).

Request – The act of a customer asking for the examination of evidence by the Laboratory.

Request Number – Unique identifier within a case for each Request for Laboratory Examination.

Root Cause – The fundamental reason for a condition adverse to quality, that, if corrected or precluded, would minimize or prevent that condition, and/or similar conditions, from occurring.

Sampling – A process or procedure whereby a part of a substance, material or item is taken for testing of a representative sample of the whole.

Section Supervisor – A Forensic Scientist E6 who has management oversight responsibility for two or more disciplines within the Laboratory.

Secured Area – Locked or otherwise limited access space under Laboratory control that has access restricted to personnel authorized by the Division Commander or designee.

Shall – A word used when an element of the management system is required.

Should – A word used when an element of the management system is recommended, but not required.

Standard Procedure – A method that specifies the steps necessary to perform a test, contains documented performance characteristics, and is published by a standards producing organization such as ASTM International (formerly known as the American Society for Testing and Materials).

Subcontractor – A non-ISP entity that conducts examinations for the Laboratory that are within the scope of the Laboratory's accreditation.

Supplemental Certificate of Analysis – A Certificate of Analysis issued when additional testing is performed on a previously examined item within the same category of testing.

Technical Review – Review of examination record and Certificate of Analysis to ensure the validity of scientific results and conclusions.

Technical Reviewer – A person with expertise gained through training and experience in the category of testing being reviewed.

Tender – Laboratory's response to a request for examination.

Test Method – A document that specifies the steps, methods, equipment, and materials necessary to perform a task properly. Test Methods are written to provide instruction and standardization for activities affecting quality.

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Traceability – Property of the result of a measurement or the value of a standard whereby it can be related to stated references, usually national or international standards, through an unbroken chain of comparisons all having stated uncertainties.

Uncontrolled Document – A document that is not distributed in a traceable manner.

Unit Supervisor – A Forensic Scientist E7 or First Sergeant who has management oversight responsibility for a specific discipline or Unit within the Laboratory.

Validation – The process of performing a set of experiments which establish the efficacy and reliability of a technique or procedure or modification thereof.

Verification – Independent review process in which a second qualified analyst examines the evidence to determine the accuracy of the finding made by the first analyst.

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4.1 Organization

- 4.1.1 The Indiana State Police Department (ISP) is authorized by Indiana Code (I.C.) 10-11-2. The Laboratory is a Division of the Indiana State Police Department and provides scientific and technical examinations of physical evidence along with crime scene processing for all criminal justice agencies within the State of Indiana. Laboratories are located in Indianapolis, Lowell, Fort Wayne and Evansville.
- 4.1.2 The Laboratory provides forensic services to address customer's requests for the examination of evidence. The tests conducted conform to the requirements of American Society of Crime Laboratory Directors/Laboratory Accreditation Board-International (ASCLD/LAB-[®]I) accreditation program.
- 4.1.3 The requirements in the Laboratory's [management system documents](#) shall be followed regardless of where work is conducted by the Laboratory personnel.
- 4.1.4 The responsibilities of Laboratory Division personnel are in [Civilian](#) and [Police Job Descriptions](#) issued by the Human Resources Division which summarizes the positions and duties.
 - 4.1.4.1 The Division Commander's and Laboratory Managers' responsibilities and authorities are defined in the job descriptions.
 - 4.1.4.1.1 The authority of the Laboratory Division Commander, Deputy Division Commander, Forensic Analysis Director, Section Supervisors, Laboratory Managers, Quality Assurance Coordinator, and Unit Supervisors are defined and commensurate with their responsibilities.

The Laboratory Division Commander and each Laboratory Manager shall organize the Division and its laboratories to maximize effectiveness through proper delegation of authority. Such delegation should be commensurate with supervisor's responsibilities and assigned to the lowest possible level.

- 4.1.5 a Laboratory Division personnel have the authority and resources needed to carry out their duties, including the implementation, maintenance and improvement of the management system, and to identify the occurrence of departures from the management system or from the procedures for performing tests and to initiate actions to prevent or minimize such departures.

Requests for a significant deviation from this Quality Assurance Manual or a Laboratory policy shall be made in writing through channels to the Division Commander. The request shall include the reason for the deviation and the

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alternate approach to be used. The Division Commander shall notify the employee and respective chain of command in writing of his decision.

- 4.1.5 b** All Laboratory personnel shall be free from any undue internal and external commercial, financial and other pressures that may adversely affect the quality of their work.

Laboratory Division personnel shall comply with all relevant rules for ethical conduct including [General Policy #041 Code of Professional Conduct](#), [ISP Regulation 1: Code of Professional Ethics](#), [ISP Standard Operating Procedure PST-011 Code of Ethics – Conflict of Interest, Gifts, and Gratuities](#), [Ethics Rules](#) from the Indiana State Code of Ethics, and [ASCLD/LAB Guiding Principles of Professional Responsibility for Crime Laboratories and Forensic Scientists](#).

- 4.1.5 c** The policy of the Laboratory is to protect the confidential information of our customers including the electronic storage and transmission of results.

Confidential information shall be released in accordance with procedure in [QAM 5.10.3.3](#).

- 4.1.5 d** The policy of the Laboratory is that personnel shall avoid conflict of interest situations.

All Laboratory personnel shall avoid conflict of interest situations including involvement in activities that would diminish confidence in their competence, impartiality, judgment or operational integrity by complying with relevant rules (procedures) for ethical conduct (see [QAM 4.1.5 b](#)).

- 4.1.5 e** [Laboratory's Organization Chart](#) (Exhibit 1) shows the organizational structure and the relationships between units. The Laboratory Division's position within ISP is shown in the [Department's Organization Chart](#) (Exhibit 2).

- 4.1.5 f** All laboratories are staffed with professional analysts, management, and clerical employees. All analysts have received specialized training in various disciplines within the field of forensic science. They are prepared and qualified to present expert testimony before courts in their respective disciplines.

- 4.1.5.f.1** Each subordinate is responsible to one supervisor for technical or administrative functions.

- 4.1.5 g** Unit Supervisors shall be familiar with analytical test methods, purpose of each test performed and the potential test results. The Units Supervisors are responsible for the technical supervision of analysts, including trainees.

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4.1.5 h The Division Commander, Director of Forensic Analysis, Section Supervisors and Unit Supervisors have overall responsibility for the technical operations to ensure the quality of laboratory results.

4.1.5.h.1 Unit Supervisors are responsible for the technical operations and quality management system of their respective unit. As the first line supervisor this is accomplished through training, a performance appraisal system, casework reviews, proficiency testing, methods and reagents validation and witness critiques. The Technical Leader is technically responsible for the operations of the Biology Section.

4.1.5 i The Director of Forensic Analysis serves as the Quality Assurance Manager with the duties and responsibilities described in the [job description](#). The Quality Assurance Manager has the responsibility and authority for ensuring that the management system documents/requirements related to quality are implemented and followed at all times.

4.1.5 j When scheduling approved time off of greater than one (1) day, Managers and Supervisors shall designate an appropriate member of the Laboratory to act in their capacity. The Manager or Supervisor shall inform, preferably by email, immediate supervisor, subordinates, and all other relevant Laboratory personnel, who has been appointed as their acting manager or supervisor.

In the event of an unexpected absence of a Manager or Supervisor, the Division Commander shall appoint an individual as the acting manager or supervisor, when necessary.

4.1.5 k Laboratory personnel are made aware of the relevance and importance of their activities and how they contribute to the achievement of the objectives of the Laboratory Division through their training, laboratory meetings and/or electronic communications.

4.1.6 All communications, both internal and external, shall be clear, concise and simply stated. Tact and diplomacy are a must in Laboratory communications. The Laboratory Division Commander and Management/Supervisory staff shall ensure that effective communication exists within the laboratory. They shall encourage direct communication between laboratories, sections and individual analysts on technical matters. "Through Channels" shall be used on administrative matters. All external and internal written communications shall follow the guidelines set forth by the Department ([SOP-PST-010](#)).

Laboratory meetings shall be conducted and documented as needed on a periodic basis for supervisory, analytical and support staff to convey information regarding policies and procedures. Division Staff, Laboratory Managers, and Unit Supervisors shall meet on a periodic basis to convey and discuss laboratory policies and procedures.

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Laboratory Managers shall meet on a periodic basis with staff to convey and discuss laboratory policies and procedures.

Unit Supervisors shall conduct meetings on a periodic basis to convey and discuss laboratory policies and procedures.

These meetings shall be documented by using a meeting sign-in sheet (e.g. [Exhibit 3](#)) and a synopsis or an agenda of the topics discussed.

Meeting documentation shall be maintained for a minimum of five years on the network drive.

- 4.1.7 The Division Commander has established and appointed Safety Officers ([Division Commander's Designee Document](#)). The duties and responsibilities are described in [Safety Policy #001](#).
- 4.1.8 The key Laboratory Management hierarchy consists of the Division Commander, Deputy Division Commander, Director of Forensic Analysis, Section Supervisors, QA Coordinator, Unit Supervisors, and Laboratory Managers.

The Division Commander, Deputy Division Commander, Director of Forensic Analysis, and Laboratory Managers are the top Laboratory Management.

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4.2 Management System

- 4.2.1** The Laboratory is committed to its management system as outlined in this Quality Assurance Manual.

The Laboratory Division shall post in each laboratory a copy of its written Mission and Operating Statements ([Exhibit 4](#)) and Unit Goals. These shall be based upon needs of our customers and the Criminal Justice System within the State of Indiana. Employees shall know their locations and understand their content.

- 4.2.2** The Laboratory is committed to applying the highest standards of professional practice and quality forensic analysis for members of the criminal justice community. The Laboratory's quality objectives are given in QAM 4.2.2.a-e below.

- 4.2.2.a** The Laboratory is committed to the implementation of sound professional practices and to maintaining or improving the quality of forensic science services provided to our customer agencies.

- 4.2.2.b** The Laboratory is committed to providing the highest standard of service.

- 4.2.2.c** The management system assures quality forensic services to our customers by promoting a professional awareness among the analysts within the Laboratory.

- 4.2.2.d** Laboratory personnel shall familiarize themselves with the relevant management system documents and adhere to the policies and procedures in their work.

- 4.2.2.e** The Laboratory shall comply with the American Society of Crime Laboratory Directors /Laboratory Accreditation Board-*International* (ASCLD/LAB-I®) accreditation requirements.

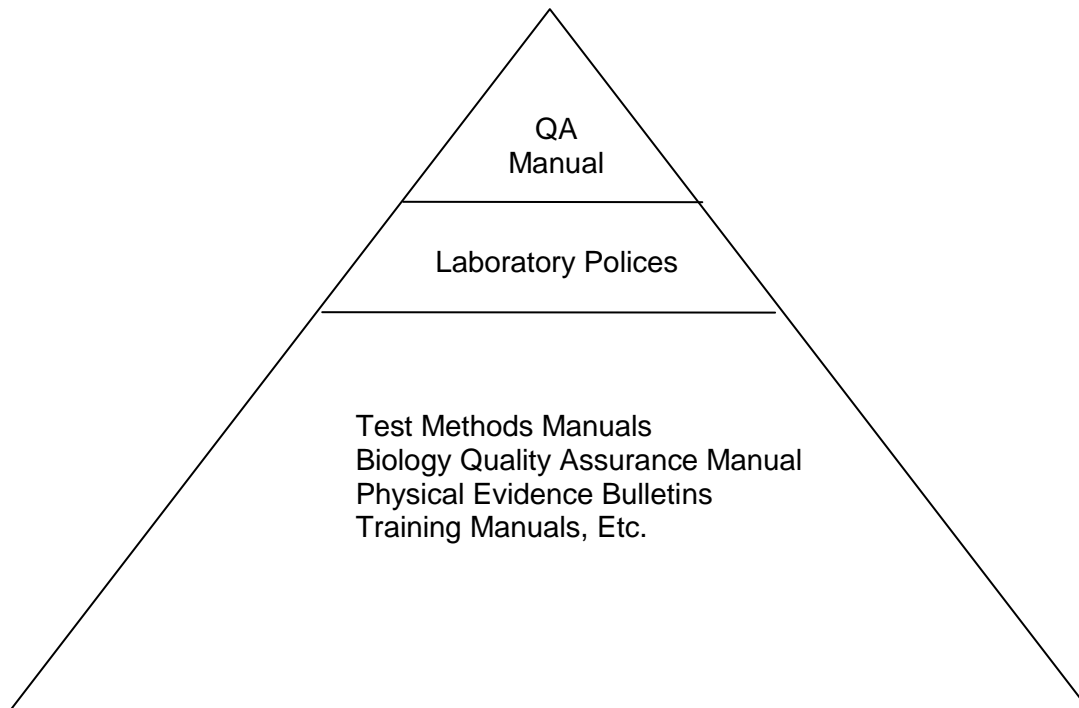
- 4.2.2.1** A copy of [ASCLD/LAB Guiding Principles of Professional Responsibility for Crime Laboratories and Forensic Scientists](#) shall be maintained on the network drive.

- 4.2.2.2** Laboratory personnel shall annually review ASCLD/LAB Guiding Principles of Professional Responsibility for Crime Laboratories and Forensic Scientists. The records of these reviews shall be maintained on the network drive.

- 4.2.3** The Laboratory has developed and implemented the management system described within this Quality Assurance Manual and is committed to continually improving its effectiveness.

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- 4.2.4** Laboratory personnel shall understand the importance of addressing customer's requests for laboratory analysis and complying with any relevant statutory and regulatory requirements.
- 4.2.5** The Laboratory's [management system documents](#) are comprised of a Quality Assurance Manual, General Laboratory and Unit Policies, Test Method Manuals, Unit Quality Assurance Manual, Training Manuals, Physical Evidence Bulletins, etc. The following outlines the structure of the documentation:



- 4.2.6** The Quality Assurance Manager is responsible overall for the quality system of the Laboratory. The responsibilities include the coordination and administration of activities required to implement and maintain quality.

Section Supervisors are responsible for the quality management system of their respective section.

The Quality Assurance Coordinator assists in the planning, directing, implementing and monitoring of laboratory quality assurance activities.

Laboratory Managers and Unit Supervisors are responsible for the quality management system of their respective unit.

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The roles and responsibilities of the Director of Forensic Analysis (Quality Assurance Manager), Section Supervisors, Quality Assurance Coordinator, Laboratory Managers and Unit Supervisor are defined in their [job descriptions](#).

- 4.2.7** The integrity of the management system shall be maintained when changes to the management system are planned and implemented.

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4.3 Document Control

4.3.1 General

The Laboratory Division management system documents provide administrative and technical operational guidelines. Management system documents are adopted in order to assure customer agencies a quality work product. Management system documents, once approved and disseminated, shall be the controlling influence for all Laboratory Division employees to follow.

The Laboratory's Management System [documents](#) shall include, but are not limited to: Policies, Quality Assurance Manual, Physical Evidence Bulletins, Tests Methods and Training Programs.

The procedures for control of internal documents are described in [QAM 4.3.2](#) and [QAM 4.3.3](#).

External Document Approval and Issue

Controlled external documents shall be reviewed and approved for use by the Division Commander. The current approved version of external documents shall be listed in the Index of External Controlled Documents or incorporated or referenced in a Test Method or other appropriate management system document. Electronic version of documents may be available on a network drive when legally permitted by copyright laws. Paper copies and other electronic storage devices (CDs, floppy disks, etc.) shall be labeled "Controlled Copy" and properly tracked to ensure that obsolete versions are not used.

4.3.2 Internal Document Approval and Issue

4.3.2.1 The Division Commander is the issuing authority and controls the management system by formulating and enforcing written policies and procedural requirements.

The current approved version of [documents](#) are listed in the Index of Management System Documents, Table of Contents of General Laboratory Policies, Table of Contents of Unit Policies or the Physical Evidence Bulletin Index.

4.3.2.2.a The official version of a management system document is maintained electronically in secure folders on a [network drive](#) by the [Division Commander's designee](#).

Printed versions are considered to be uncontrolled copies made for reference purposes and shall be destroyed when the immediate use of the copy is no longer necessary.

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Division Commander's designee shall notify appropriate laboratory staff of changes to the management system documents. Laboratory staff shall review and familiarize themselves with the management system documents pertaining to their work.

- 4.3.2.2.b** When any employee discovers the need for a new or revised policy and/or procedural requirements, the area of concern shall be brought to the attention of the Laboratory Division Commander through channels.

The laboratory's management system documents shall be reviewed annually by the appropriate supervisory personnel assuring their continued suitability. The reviewer of the document shall complete a Document Control Ledger (e.g. [Exhibit 5](#)).

A copy of the Document Control Ledger and revision proposal(s) shall be routed through the Quality Assurance Manager to the Division Commander for approval.

The Quality Assurance Manager following a review of revised document(s) shall initial the Document Control Ledger in the comments area.

Prior to issue for use, the Division Commander shall review and approve any new or revised management system documents by initialing and dating the "Document Control Ledger".

The "Document Control Ledger" shall be stored in an electronically secure folder on a [network drive](#).

- 4.3.2.2.c** When a document revision is approved, the previous version shall be promptly moved to an archive folder on a [network drive](#).
- 4.3.2.2.d** Previous document versions shall be stored in electronically secured archived folders on a [network drive](#) and identified as an "Archive Copy".
- 4.3.2.3** The date of issue or revision, page numbering, the total number of pages, and the issuing authority shall be affixed to the document by the [Division Commander's designee](#).

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4.3.3 Internal Document Changes

4.3.3.1 The Division Commander reviews and approves all document revisions.

4.3.3.2 Revisions and/or new texts for review shall be identified in the document by using, for example, red lettering.

4.3.3.3 Handwritten revisions to management system documents are not permitted.

4.3.3.4 Management system documents are maintained electronically on a secure [network drive](#) as described previously in this section of the Quality Assurance Manual.

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4.4 Review of Requests, Tenders and Contracts

- 4.4.1** The policies and procedures for submission of evidence to laboratory are in the Physical Evidence Bulletins, Evidence Policies and Information for Customers.

The customer shall indicate on the Request for Laboratory Examination Form ([Exhibit 6](#)) or electronic equivalent the type of evidence submitted and examination requested. Laboratory personnel shall ensure that the laboratory offers the appropriate test method for the customer's request prior to accepting the evidence.

- a.** By submitting evidence to the Laboratory the customer(s) agrees to allow the laboratory to select the test methods to be used to analyze the evidence.
 - b.** The Division Commander shall ensure that the Laboratory has the capability and resources for the services offered.
 - c.** The analyst shall select the appropriate test method to analyze the evidence.
- 4.4.2** A copy of the Request for Laboratory Examination Form, if submitted by the customer, shall be maintained in the case record. (Information from the electronic equivalent shall be maintained in LIMS.) Pertinent discussion and communication regarding the customer's request shall be recorded in the case record.
- 4.4.3** The Laboratory's review of submission documentation shall also cover any subcontracted cases.
- 4.4.4** The customer shall be informed of any significant deviation from the requested analysis and documented in the case record.
- 4.4.5** The Laboratory shall work with the customer if an amendment is needed to the type of testing requested. Any amendments to the requested analysis shall be communicated to the customer.

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4.5 Subcontracting

- 4.5.1** The Laboratory shall only use subcontracting vendors where objective evidence of their competence exists.

The competence of a subcontracting vendor shall be determined by a review of that laboratory's operation by a committee made up of the pertinent Unit Supervisor, Section Supervisor and Quality Assurance Manager.

At the conclusion of a review, the committee shall, in writing, make a recommendation to the Division Commander as to whether or not a particular vendor meets the necessary levels of competency.

- 4.5.2** The Laboratory shall inform the customer(s) of the subcontracting arrangement via a Certificate of Analysis.
- 4.5.3** The Laboratory is responsible to the customer for the subcontractor's work, except in the case where the customer or a regulatory authority specifies which subcontractor is to be used.
- 4.5.4** The Division Commander shall establish a [list of vendor laboratories](#) deemed competent for subcontracting. Records establishing competence of the subcontractor shall be maintained.

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4.6 Purchasing Services and Supplies

- 4.6.1** The Laboratory's purchasing policy is that supplies, equipment and services of the required quality shall be purchased by the laboratory following State purchasing procedures.

The following procedure shall be used when ordering supplies, equipment and services. The laboratory staff shall follow Indiana Department of Administration and Indiana State Police Fiscal Division rules and regulations.

A description of the specifications and requirements for the supplies, equipment and/or services to be purchased shall be described in the Statement of Justification (SOJ) and/or the supporting documentation.

The Division Commander shall designate a person to conduct an administrative review and approve or reject SOJs prior to forwarding to the Fiscal Division.

The purchasing documentation shall be forwarded to and maintained by the Fiscal Division.

- 4.6.2** Laboratory personnel shall verify that the supplies, equipment and services received comply with the specifications, requirements and quantity. The Laboratory shall work with the Fiscal Division to resolve any discrepancy.

Laboratory personnel shall document the compliance with specifications and/or requirements of the test methods or SOJ by stamping and/or signing off on receipts, packing slips and/or invoices and forwarding to the Fiscal Division for payment. This can also be accomplished via e-mail correspondence with Fiscal Division.

- 4.6.3** The individual requesting the purchase of supplies, equipment and services, shall review the SOJ and any attached supporting documentation for technical accuracy prior to forwarding it to a Laboratory Manager, Unit Supervisor or Section Supervisor.

The Laboratory Manager, Unit Supervisor or Section Commander shall review and approve the purchasing documents prior to forwarding to Fiscal Division.

- 4.6.4** Unit Supervisors shall identify and evaluate suppliers of critical consumables, supplies and services which affect the quality of testing.

Vendors of critical consumables, supplies and services shall be listed in the Unit's test method or other appropriate manual (e.g. [Biology's Critical Reagents Manual](#)). The Division Commander shall approve the Unit's documents listing the vendors of critical consumables, supplies and services following the procedure in [QAM 4.3](#).

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4.7 Service to the Customer

- 4.7.1** Laboratory personnel shall work cooperatively with our customers to clarify their analytical requests.
- 4.7.2** The Laboratory shall seek feedback from our customers through periodic surveys and witness critiques.

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4.8 Complaints

Customers/Other Parties Complaints

- 4.8** The Laboratory shall follow the [Department's Citizen Complaint](#) procedure for a complaint received from customers or other parties.

Employee Complaints

- 4.8.1** The Laboratory policy for employee complaints is the following: Laboratory shall investigate all complaints received from employees concerning the quality management system.

The following procedure shall be used for employee complaints. In the event an employee identifies a potential quality management system deficiency or a concern about the quality of the laboratory work, the employee shall advise supervisory staff of their concerns or issues.

Quality management system concerns or complaints shall be made in writing, and submitted through channels, to the Quality Assurance Manager.

The Quality Assurance Manager or designee shall investigate all complaints received from employees concerning quality of the laboratory work.

The Quality Assurance Manager shall, if necessary, implement a Corrective Action (see [QAM 4.11](#)).

The Quality Assurance Manager shall respond in writing to each complaint received regardless of the severity of the concern, through channels, to the reporting party.

The records of the complaint, investigation, and response shall be maintained on a network drive for a minimum of five years.

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4.9 Control of Non-conforming Testing Work

- 4.9.1** Laboratory policy requires that all non-conforming testing work be evaluated and appropriate correction(s) and/or corrective action(s) made.

The following procedure shall be implemented when any aspect of testing work or the results do not conform to the test method.

- a.** The Quality Assurance Manager is responsible for the overall management of non-conforming work. Unit Supervisors are responsible for non-conforming work within their area of responsibility. The Unit Supervisor shall notify the Quality Assurance Manager of the non-conforming work.

The Division Commander shall authorize the halting of case work.

- b.** The Quality Assurance Manager working with supervisory staff (when applicable shall include Biology Section Technical Leader) shall assess the nature and significance of the non-conforming work.
- c.** Correction(s) shall be prompt and appropriate given the acceptability of the nonconformity.
- d.** When necessary, the customer(s) shall be notified of the non-conforming work and the corrective action measures.
- e.** The Division Commander shall authorize the resumption of case work.

Non-conforming work may be identified and brought to the attention of laboratory management through a variety of avenues including but not limited to technical case review, administrative case review, proficiency testing, witness critique, annual performance appraisal, etc.

- 4.9.2** When the evaluation indicates that the nonconformance could reoccur or there is doubt about the compliance with laboratory policies and procedures, the corrective action procedures in [QAM 4.11](#) shall be promptly followed.

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4.10 Improvement

- 4.10** Quality is attained and sustained through the active participation of all Laboratory staff. Towards that end, employees are encouraged to maintain vigilance in their observations and review of quality assurance related activities.

The Laboratory is committed to continued improvement of the effectiveness of the management system through the use of the following:

- Quality Policy and Objectives ([QAM 4.2.2](#))
- Audit Results ([QAM 4.14](#))
- Analysis of Data ([QAM 5.9.2](#))
- Corrective Actions ([QAM 4.11](#))
- Preventive Actions ([QAM 4.12](#))
- Management Review ([QAM 4.15](#)).

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4.11 Corrective Action

4.11.1 General

The Laboratory policy requires a corrective action to be implemented when non-conforming work (departures from policies and procedures) in the quality management system or technical operations has been identified.

The following procedure shall be used for corrective actions. The Quality Assurance Manager shall be notified through channels of the potential need to implement a corrective action.

The Quality Assurance Manager working with the reporting party and supervisory staff (when applicable shall include Biology Section Technical Leader) shall assess the magnitude and risk of the non-conforming work.

The Quality Assurance Manager shall make the determination as to whether or not a corrective action is warranted based on discussions with the reporting party and staff and reviewing the supporting documentation. A corrective action shall be implemented when the nature and cause of the nonconformity raises immediate concern regarding the quality of the laboratory work.

In the event that the Quality Assurance Manager decides a corrective action is warranted, a corrective action number shall be drawn and entered onto the Corrective Action Log (e.g. [Exhibit 7](#)).

A Corrective Action Report ([Exhibit 8](#)) shall be completed by the reporting party, in conjunction with the supervisory staff and Quality Assurance Manager as designated on the form.

The final review and approval for a corrective action and authorization for the resumption of case work shall be by the Division Commander.

A Corrective Action Report and supporting documentation shall be maintained for a minimum of five years.

With authorization from the Quality Assurance Manager, nonconformities that have minimal effect or significance, be unlikely to recur, are not systematic, or does not significantly affect the fundamental reliability of the laboratory's work may be addressed by the Unit Supervisor and documented in the case record or fact file of the analyst.

4.11.2 Cause Analysis

Corrective action shall start with an investigation in an effort to determine the root cause(s) of the problem.

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4.11.3 Selection and Implementation of Corrective Action

When corrective action is needed, the Laboratory shall select and implement the action(s) most likely to eliminate the problem and to prevent recurrence.

Corrective actions shall be to a degree appropriate to the magnitude of the problem.

The Laboratory shall document and implement any required changes resulting from corrective action investigations.

4.11.4 Monitoring of Corrective Actions

The Laboratory shall monitor the results to ensure that the corrective actions taken have been effective.

4.11.5 Additional Audits

The Laboratory shall conduct additional audits, when warranted, of appropriate laboratory operations in accordance with [QAM 4.14](#).

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4.12 Preventive Action

- 4.12.1** The laboratory shall implement a preventive action plan when a potential source of non-conformity is identified.
- 4.12.2** Employees shall identify opportunities for improvement and potential sources of nonconformities in either technical operations or management system.

Employees shall notify in writing, through channels, the Quality Assurance Manager when an opportunity for improvement or a potential source of non-conformity is identified.

The Quality Assurance Manager or designee shall evaluate all opportunities for improvement or potential sources of non-conformity received.

If a preventive action is not warranted, the Quality Assurance Manager or designee shall respond in writing, through channels, to the employee explaining why the preventative action is unnecessary.

When a preventive action is required, the Quality Assurance Manager or designee shall develop, implement and monitor an action plan to reduce the likelihood of the occurrence of the non-conformity and to take advantage of the opportunities for improvement. Actions taken during the preventative action shall be documented.

When necessary, quality control measures shall be initiated to ensure that the actions taken are effective.

The records of the preventive actions shall be maintained for a minimum of five years on a network drive.

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4.13 Control of Records

4.13.1 General

- 4.13.1.1** The Certificate of Analysis, laboratory case notes and other related documentation other than maintenance and calibration records shall be retained in the case record in an electronic format. The case records shall be stored under the laboratory case number.

The case record shall be maintained on approved network drive. Any printouts of reports, charts, graphs or photographs which are retained by any authorized personnel, i.e. prosecutors, investigators or courts, shall be recorded by the analyst on the "Record of Dissemination" in LIMS. Any printout, used by the analyst and not given to authorized personnel, shall be destroyed by the analyst after use.

[General Policy #037 Laboratory Information Management System](#) and [Imaging Module Instructions](#) shall be followed.

- 4.13.1.2** Electronic version of case records stored in LIMS or a network drive shall be maintained indefinitely. Case records shall only be destroyed with authorization by the Division Commander.
- 4.13.1.3** All records shall be maintained in a secure LIMS or a network drive and the information contained therein maintained in strict confidence.
- 4.13.1.4** The LIMS provides standard reports to assist in the management of the laboratory. Certificate of Analyses are available within the system and accessible by all laboratory employees who have access to the LIMS.

Records stored on network servers are backed-up by the Indiana Office of Technology (IOT).

A password is required to access department computers and network drives.

Amendments to records on LIMS are tracked by an audit trail.

Also see [General Policy #037 Laboratory Information Management System](#).

4.13.2 Technical Records

- 4.13.2.1** Laboratory notes shall be generated for all cases analyzed and shall be maintained in the case record in LIMS.

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The case record shall accurately record and maintain observations, data, and calculations made during the analysis of evidence samples.

The case record shall include a description of, the condition of, and identification of evidence items.

The case record shall specify the method(s) and/or technique(s) used to analyze the evidence.

4.13.2.2 Observations, data and calculations shall be recorded contemporaneous to being made. The original recordings shall be maintained in the case record as part of the examination records.

4.13.2.2.1 The starting date for casework testing is the date the evidence is unsealed and/or inventoried by the analyst. The ending date of analysis is the date that the case is submitted for administrative and/or technical review. Dates shall be recorded as to when the work is performed.

4.13.2.3 When striking out a letter or number on a hardcopy of the case record, a single line shall be drawn through the correction and initialed.

4.13.2.3.1 Any change made to the hardcopy of the case record shall be initialed by the person making the change.

4.13.2.3.2 Any changes made to completed examination records generated and/or maintained in an electronic form shall be tracked by saving the changed page of the examination records in LIMS. Examination records shall be considered completed when submitted for administrative and/or technical review.

4.13.2.4 Administrative and examination records from a particular case constitutes a "case record".

Examples of administrative records includes: Certificates of Analysis, Request for Laboratory Examination form, evidence receipts, dissemination records, subpoenas, etc.

Examples of examination records includes: notes regarding tests, charts, graphs, printouts, photographs, results of testing, etc.

4.13.2.5 Examination records shall be of sufficient detail that a technically qualified peer could review this documentation and interpret the data.

4.13.2.5.1 The Latent Print Unit shall meet all applicable requirements in

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ASCLD/LAB-I Supplemental Requirements Appendix C Latent Print Examination Records, in addition to meeting all applicable requirements specified in [QAM 4.13](#).

4.13.2.5.2 When instrumental analyses are conducted, operating parameters shall be recorded. Operating parameters may be documented in the test method, recorded in a log book or recorded in the examination records.

4.13.2.6 The laboratory case number and original handwritten analyst's initials shall be on each page of the hardcopy of examination records. Item number(s) shall be recorded where appropriate.

Each page of examination records generated and maintained electronically shall have the laboratory case number and analyst's typed initials or name. Note: Saving the examination records in the Laboratory Information Management System (LIMS) shall be considered a secure electronic equivalent to a signature of the analyst.

The laboratory case number and analyst's initials or name should appear in the digital images. When not practical, the file name of the digital images shall, at a minimum, have the laboratory case number and analyst's initials, name or permanent employee (PE) number.

It is recommended for each examination record a page numbering system be used (e.g. page of).

4.13.2.7 When examination records are prepared by an individual(s) other than the analyst who interprets the findings, prepares the Certificate of Analysis and/or testifies concerning the records, the handwritten initials (or secure electronic equivalent of initials or signature) of that individual(s) shall be on the page(s) of examination records representing his work.

4.13.2.8 All administrative records contained within the case record, both hardcopy and electronic, shall be identified with the laboratory case number. Submitted records received bundled and/or stapled may be considered a single record and may be identified with the laboratory case number on the front page of the record. Item number(s) shall be recorded where appropriate.

4.13.2.9 When data from multiple cases are recorded on a single printout, the laboratory case number of each case shall be appropriately recorded on the printout.

4.13.2.10 When both sides of a page are used for hardcopies, each side shall be treated (identified with laboratory case number and initialed) as a separate page.

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- 4.13.2.11** Examination records shall be permanent in nature. Notes, worksheets and other writings in a case record shall be made in ink or electronically. Unit Supervisor's may approve exceptions to using ink.
- 4.13.2.12** Verifications shall be performed by individuals with expertise gained through training and experience. The case record shall indicate that the verification was performed, agreed to, by whom, and when performed. Additional instructions for verification are in the applicable test method.
- 4.13.2.13** Abbreviations may be used if universally recognized or when a key is provided in the case record or the test method.

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4.14 Internal Audits

- 4.14.1** The following procedures shall be used to conduct annual internal audits of the Laboratory. The Quality Assurance Manager and designated staff members shall conduct internal audits at each laboratory using the current version of ASCLD/LAB Field Assessment Guide.

The Quality Assurance Manager shall ensure staff performing the internal audits are properly trained, qualified, and wherever resources permit, independent of activity to be audited. Records of this training shall be maintained on a network drive.

Biology personnel shall conduct an annual audit of the current criteria established by the Federal Bureau of Investigation ("Quality Assurance Standards for Forensic DNA Testing Laboratories" and "Quality Assurance Standards for DNA Databasing Laboratories"). At least every two years, an external agency shall perform an audit.

Laboratory Division Staff shall conduct staff inspections with respect to criteria which fall outside the scope of ASCLD/LAB accreditation and the Biology Section audits.

During the process of an audit, the auditing personnel shall consult with other laboratory staff to ensure that all significant changes that were made in the past year to staff, facilities, services, or procedures are documented in the audit reports.

- 4.14.1.1** Required internal audits shall be conducted at least once during the calendar year at all regional laboratory facilities.
- 4.14.1.2** All audits shall be completed and reports prepared by the required deadline. The individual reports shall be signed indicating that the laboratory met all standards and criteria or the necessary remedial action has been initiated.

All reports shall be forwarded to the Division Commander for review. Upon review by the Division Commander, the internal audit reports shall be forwarded to the accrediting body as required.

A copy of the Staff Inspection Report and ASCLD/LAB Field Assessment Guide shall be maintained on a network drive for a minimum of five years. The Technical Leader shall maintain a copy of the Biology Section Audit Reports.

- 4.14.2** Any nonconformance in standards or established criteria shall be documented and accompany the audit reports describing the remedial action to be taken

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and a time line for completion. The customers shall be notified when internal audits show that the analytical results may have been affected.

- 4.14.3** The area of the laboratory audited, the audit findings and corrective actions shall be recorded in the audit documentation.
- 4.14.4** Follow-up audit activities shall verify and record the implementation and effectiveness of the corrective action taken.
- 4.14.5** The Quality Assurance Manager shall submit an Annual Accreditation Audit Report to ASCLD/LAB as required.

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4.15 Management Review

- 4.15.1** The following procedures shall be used to conduct the annual management review of the Laboratory. The purpose of management reviews is to evaluate the Laboratory's management system and testing activities to ensure their continuing suitability and effectiveness, and to introduce necessary changes or improvements.

The Division Commander, Deputy Division Commander, Quality Assurance Manager, Section Supervisors, Laboratory Managers, Unit Supervisors, and Quality Assurance Coordinator shall annually meet and review the management system.

The Quality Assurance Manager shall organize the management review meeting. The review shall cover the following since the last management review:

- Suitability of policies and procedures;
- Reports from managerial and supervisory personnel;
- Internal audits;
- Corrective and preventive actions;
- External assessments;
- Proficiency tests;
- Changes in type and volume of work;
- Customer feedback;
- Quality Assurance related complaints;
- Recommendations for improvement;
- Other relevant factors, such as quality control activities, resources, and staff training.

- 4.15.1.1** The Laboratory shall conduct a management review annually within 60 days of the completion of the annual internal audits reports.

- 4.15.1.2** Records from the management review shall be maintained for a minimum of five years on a [network drive](#).

- 4.15.2** Findings from the management review meeting and actions taken shall be recorded.

The Division Commander shall ensure that plans of actions that result from the management review are completed in an appropriate time frame.

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5.1 General Technical Requirements

- 5.1.1** Many factors determine the correctness and reliability of the tests performed by the Laboratory. These factors include contributions from:
- personnel ([QAM 5.2](#));
 - accommodation and environmental conditions ([QAM 5.3](#));
 - test methods and method validation ([QAM 5.4](#));
 - instrument/equipment ([QAM 5.5](#));
 - measurement traceability ([QAM 5.6](#));
 - sampling ([QAM 5.7](#));
 - and the handling of evidence ([QAM 5.8](#)).
- 5.1.2** The Laboratory shall take into account the factors contributing to the uncertainty of measurement when developing test methods and procedures, in the training and qualification of personnel and in the selection and calibration checks of the instruments it uses.
- 5.1.3** Test methods shall include procedures used to verify the reliability of the reagents. The routine recorded use of appropriate controls is a suitable method to ensure the continued reliability of reagents.
- 5.1.3.1** Reagents prepared in-house shall be labeled with the reagent name, preparer and date of preparation or lot number.

The reagent reliability testing shall be performed and evaluated prior to or contemporaneous with the initial use and on a routine basis thereafter. Reagents reliability testing shall be documented in either a log, in the examination records or on a network drive including the following:

- Reagent name
- Date of preparation
- Preparer
- Reliability was tested
- Reagent worked as expected

The reagent logs or electronic equivalent shall be maintained for at least five years.

Chemicals or reagents used in laboratory analysis shall not be used beyond their expiration date.

Chemicals and reagents used in laboratory analysis received after March 20, 2007 shall be labeled with the date of receipt and the initials of the individual receiving the material.

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Those chemicals and reagents used in laboratory analysis received on or before March 20, 2007, which are not marked, shall be marked with a red sticker and initialed.

The chemicals, reagents and other laboratory consumable materials shall be stored in a way to ensure quality and safety. Due regard shall be given to the manufacturer's recommendations on storage and shelf life.

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5.2 Personnel

5.2.1 Staffing the Laboratory shall follow the procedures outlined in the Indiana State Police Regulations and by the Human Resources Division. It is the desire and intent of this Laboratory to employ only the highest qualified persons.

The Division Commander shall ensure the competence of all analysts. Analysts shall be qualified on the basis of appropriate education, training, experience and/or demonstrated skills.

The Unit Supervisor coordinates and oversees the training of analysts.

5.2.1.1 Each Unit shall have a training manual(s) available on a [network drive](#) used to train individuals in the knowledge, skills, abilities, and specific equipment needed to perform the testing. Training manual components may vary slightly from unit to unit, but shall address test methods and courtroom testimony. Supervisors may include other components they deem necessary for their particular discipline. To ensure continuing suitability, each training manual shall be reviewed annually by the appropriate supervisor responsible for that discipline as specified in [QAM 4.3](#). Changes made to the training program shall be reflected, where appropriate, in the respective test method.

The Division Commander may require that Laboratory personnel successfully complete a retraining program as a result of the use of extended leave time, noncompliance with Quality Assurance Standards or any other scenario which indicates the possibility of diminished proficiency.

When retraining of personnel is necessary, the respective Unit Supervisor or Technical Leader may use the existing training manual or develop a new module as required. After the retraining is completed, the Division Commander shall authorize the return to casework.

The Laboratory is committed to the professional development of employees through membership in professional organizations, attending meetings and seminars and reading of library reference materials.

The Department may pay membership dues, if funds are available, for any employee eligible for membership in one forensic related professional organization on a yearly basis. The request of payment for membership dues in a forensic related professional organization shall be made through channels to the Division Commander.

Employees are encouraged to attend professional meetings and seminars related to their job responsibilities. If sufficient funds are available, the

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employee may be reimbursed for the cost of attending a professional meeting to include but not limited to registration fees, travel, per diem and lodging.

It is the responsibility of supervisory staff to identify training needs and prepare training requests to send to the Training Division through proper department channels.

Laboratory Managers and Unit Supervisors shall allow and encourage employees to take up to 3 hours of their work time per week to read periodicals, journals, articles, books, web pages, etc. related to their discipline in order to maintain their knowledge, expertise and/or prepare for individual certification.

In order to ensure that relevant information is disseminated in a timely manner, Laboratory Managers and/or Unit Supervisors may use a router or e-mail to circulate amongst employees relevant reading materials or copies of their table of contents.

- 5.2.1.2** It is the responsibility of Laboratory personnel to understand the principles, methods and techniques of their particular position and be able to effectively communicate this knowledge in the courtroom.

All trainees shall successfully complete at least one mock trial during training prior to assuming casework responsibilities.

The mock trial shall simulate a real courtroom experience. The witness and primary participants should dress and act accordingly.

The trainee's supervisor or trainer is responsible for the coordination of the mock trial and ensuring a representative cross section of Laboratory Division personnel are present by giving at least 24 hours advance notification. Attendance requires preapproval from immediate supervisor.

The trainee shall have completed the examination or processing of mock evidence and have generated a discipline relevant report.

Prior to the mock trial, the trainee shall provide a complete copy of any and all records requested to the acting prosecutor and defense attorney.

The mock trial shall consist of, at a minimum, the swearing in of the witness, direct examination, cross-examination, and witness critique.

All attendees at the mock trial should evaluate the witness' performance using the Courtroom Evaluation Rating Sheet ([Exhibit 9](#)).

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The mock trial and subsequent witness critique shall be video recorded. After the mock trial, the supervisor and the trainee shall review the video recording and rating sheets. The video recording and rating sheets shall be discarded after successful conclusion of the mock trial training exercise.

- 5.2.1.3** Ethical practices in forensic sciences and a general knowledge of forensic science shall be components of the [New Employee Orientation Training Manual](#).

Applicable criminal and civil law and procedures shall be included in the Unit's training manual(s).

- 5.2.2** This Laboratory policy is to identify training needs and provide relevant training to personnel.

The following procedure shall be used to identify training needs and provide training to Laboratory personnel. Each fiscal year, Section Supervisors shall consult with the Units Supervisors to identify the relevant training needs within their respective section and submit their requested training to the Division Commander. The Division Commander shall formulate the training budget/goals for the Laboratory Division. Training requests should be submitted for training using the approved budget. Personnel attending external training should submit in writing or give an oral evaluation of the training. The supervisor shall retain any written evaluations in the attendee's fact files.

The effectiveness of the internal discipline or category of testing training programs shall be evaluated by the trainee's performance on the written exams, competency tests, practical exercise, and/or mock trial results.

- 5.2.3** Laboratory Division personnel are employees of the Indiana State Police Department.

- 5.2.4** Job descriptions for all [civilian](#) and [police](#) Laboratory Division personnel are maintained by the Department's Human Resources Division and are available on a network drive.

- 5.2.5** A Laboratory Training Record (see [Attachment 1 to General Policy #002 Laboratory Training Manuals](#)) shall be contemporaneously completed following the successful completion of each module, section, or unit of training of the program.

The trainer shall maintain all written tests, competency tests, practical exercise results, and other documentation with the completed ISP Laboratory Training Records in a secure file until the entire program is successfully completed.

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Following the successful completion of a training program, the respective Unit Supervisor or Technical Leader shall make written recommendations, through channels, to the Division Commander as to the employee's status to perform actual case work.

The Division Commander may authorize an employee to perform actual case work which includes conducting tests, issuing Certificate of Analysis, giving results, opinions and interpretations and operating instruments/equipment required in the discipline or category of testing. The Division Commander shall notify the employee and respective chain of command in writing of his decision in this regard.

At the end of a training program, all completed Laboratory Training Record forms shall be compiled and forwarded to the Division Commander. The Division Commander shall maintain these records in the Division's administrative information files throughout the employment of the individual and ten (10) years after the person has left the employment of the Department.

All the remaining records of the training program shall be submitted to the appropriate Unit Supervisor. The file shall be securely maintained as hardcopies or electronically on a network drive for at least five (5) years after which the file may be purged with approval of the Laboratory Division Commander.

5.2.6 Technical Personnel Requirements

5.2.6.1 Education

5.2.6.1.1 Analysts working in Drug and Trace Units shall meet all requirements in their respective [job description](#) including a baccalaureate degree in a natural science or forensic science.

5.2.6.1.2 Not applicable.

5.2.6.1.3 Analysts working in Biology Section shall meet all requirements in their respective [job description](#) including a baccalaureate degree in biology, chemistry or forensic science.

5.2.6.1.4 Analysts working in Firearms, Documents or Latent Prints Units shall meet all requirements in their respective [job description](#) including a baccalaureate degree.

5.2.6.1.5 Not applicable.

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5.2.6.2 Competency Testing

5.2.6.2.1 All trainees, regardless of academic qualifications or past work experience, shall satisfactorily complete a competency test in each category of testing prior to assuming casework responsibility.

5.2.6.2.2 Competency tests for analysts shall include, at a minimum:

- Examination of sufficient number of unknown samples to cover the anticipated spectrum of assigned duties and evaluation of the analyst's ability to perform proper testing methods;
- A written report to demonstrate the analyst's ability to properly convey results and/or conclusions and the significance of those results/conclusions; and
- A written and/or oral examination to assess the analyst's knowledge of the discipline, category of testing, or task being performed.

5.2.7 A spreadsheet of the inventory of the Laboratory's library reference materials (e.g. [Exhibit 10](#)) shall be maintained on the network drive. The spreadsheet includes all books, CDs or DVDs and other library reference materials.

The Supervisors located at the Indianapolis Regional Laboratory (IRL) and the Laboratory Managers or their designee at all four laboratories are responsible for keeping the spreadsheet up to date when new library reference materials are received and obsolete library reference materials are disposed.

A Library Reference Material Sign Out Log (e.g. [Exhibit 11](#)) shall be maintained by the Supervisors in Indianapolis and the Laboratory Managers or their designee at all four laboratories. Employees shall complete the Library Reference Material Sign Out log when any item is borrowed and returned.

All library reference material shall be clearly marked as property of the Indiana State Police Department.

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5.3 Accommodation and Environmental Conditions

5.3.1 Laboratory facilities' environmental conditions shall facilitate accurate performance of analytical tests.

The Laboratory shall ensure that the environmental conditions do not invalidate the results or adversely affect the required quality of any measurement. The technical requirements for accommodation and environmental conditions that can affect the results of tests shall be documented in the appropriate Test Method.

In order for the laboratory to efficiently carry out its goals and objectives, adequate space shall be allocated for each laboratory activity and/or function.

Each employee shall be provided enough working space to efficiently accomplish their assigned duties without the risk of mishandling or contamination of evidence. Each employee's working area and general laboratory working areas shall have sufficient drawers, cabinets, shelves or other storage space provided for proper storage and handling of individual and general laboratory supplies, equipment and other tools necessary to carry out their assigned duties.

Laboratory supervisory personnel shall have space available for report writing and storage of official laboratory records necessary for their assigned duties.

The laboratory shall have space designated for the safekeeping of official laboratory records, reports, library reference materials, books and other documents necessary for carrying out the functions of the laboratory.

Evidence shall be maintained in secured evidence storage for long-term storage and each analyst shall have a secured storage area for overnight or short-term storage of evidence material.

Storage areas shall be provided for laboratory clerical supplies in excess of short-term storage use.

Proper and sufficient space shall be provided for long-term storage of volatile and flammable materials.

Sufficient space shall be provided for each instrument (and accessories) to facilitate its proper and most efficient use and operation.

The design of the facility shall be organized to maximize the functions and activities of the laboratory, to safeguard the physical evidence, and to protect the confidential nature of the laboratory operation. It shall be designed to provide a safe and healthy working environment.

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A physical design shall be employed which enhances the flow of evidence from the time of its acceptance until its proper disposal.

All laboratory working and examination areas shall have proper lighting to enable personnel to safely and efficiently carry out their assigned duties. The laboratory shall be equipped with proper plumbing and wiring to comply with existing safety codes. The laboratory shall be properly ventilated with fume hoods available to remove toxic and/or noxious fumes and any other ventilation necessary for the health and safety of the laboratory personnel.

- 5.3.2** Analysts shall monitor, control and record environmental conditions as required by Test Methods or where they influence the quality of the results. Due attention shall be given, for example, to biological sterility, dust, electromagnetic disturbances, radiation, humidity, sound and vibration levels, electrical supply, and temperature, as appropriate to the technical activities concerned. Tests shall be stopped when the environmental conditions jeopardize the results of the tests.
- 5.3.3** There shall be effective separation between neighboring areas in which there are incompatible activities. Measures shall be taken to prevent contamination.
- 5.3.4** Access to and use of the laboratory is controlled by the procedures in QAM 5.3.4.1.a-f below.
- 5.3.4.1.a** During business hours unauthorized access to the laboratory shall be prevented by a barrier installed at the foyer entrance.

Access to the laboratory shall be permitted upon the authorization of a laboratory employee. The authorizing laboratory employee shall ensure that a visitor log entry is made and a visitor tag is worn. Individuals providing recurring goods or services are exempt from signing the visitor log. Those exempt should wear a visitor tag.

The authorizing laboratory employee shall ensure that the visitor is escorted by laboratory personnel at all times. State Police personnel assigned to or conducting business at a regional laboratory, wearing a recognizable uniform or prominently displayed identification badges, or are known and recognizable by Laboratory Division personnel do not need to sign the visitor log or wear a visitor tag but shall be escorted.

(Excluding the Indianapolis Regional Laboratory) District Post Command who must enter after-hours shall perform the following:

- Post Command shall inform the Laboratory Manager when after hours entry was required.

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- Post Command gains entry via a key secured in a sealed envelope that is maintained in a secure location.
- Once the key is utilized it must be resealed in an envelope by the Laboratory Manager or his designee.

Custodial and maintenance personnel permitted access by laboratory personnel are exempted.

5.3.4.1.b The laboratory building shall have adequate security.

5.3.4.1.c Internal laboratory area requiring limited/controlled access shall have a lock system.

5.3.4.1.d The [Division Commander or his designee](#) shall maintain strict control of all keys and access identification cards for the evidence system through the use of signature cards and other appropriate records (see [General Policy #004 Security of Evidence Keys](#)).

5.3.4.1.e When the laboratory is unoccupied the outer doors shall be locked and external alarms activated. The Laboratory Manager shall verify and document monthly in a log that the alarms are functioning. This verification can be accomplished by testing the alarms or by documenting the active alarms such as door alarms at the Indianapolis Regional Laboratory (IRL). The Laboratory Manager shall maintain the records of these checks for a minimum of five (5) years.

5.3.4.1.f Evidence storage areas shall be secured with controlled access to prevent theft or interference. The storage conditions both before and after examination shall prevent loss, deterioration and contamination and shall maintain the integrity and identity of the evidence. See [Evidence Policies](#) for evidence storage procedures.

5.3.5 In order to maintain and improve the environmental conditions of the laboratory, all employees must dedicate themselves to maintaining the physical appearance of the laboratory in a clean, safe and orderly manner.

Each employee is responsible for the appearance of his/her desk, work area, and other areas as assigned and shall maintain the area of responsibility in a safe and orderly manner by applying good housekeeping practices.

5.3.6 It is the responsibility of the laboratory management personnel to provide for a safe, efficient working environment for all employees including the training of laboratory personnel in safe laboratory practices.

It follows that it is the responsibility of all employees to conduct their work in a safe manner within their scientific knowledge, training and experience.

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The Laboratory's health and [safety program](#) is documented in the Safety Manual, Chemical Hygiene Plan, Bloodborne Pathogens Exposure Control Plan, [Safety Policies](#), etc.

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5.4 Test Methods and Method Validation

5.4.1 General

The Units shall use appropriate methods and procedures for all tests performed. These include sampling, handling, storage and preparation of items to be tested and, where appropriate, an estimation of the uncertainty of measurement and statistical techniques.

The Units shall have instructions on the use and operation of all relevant instrument/equipment and on the handling and preparation of items for testing, where absence of such instructions could jeopardize the results of test.

All Test Methods shall be kept up to date and shall be available on a network drive (see [QAM 4.3](#)).

Realizing the variation in submitted cases, minor deviation from the Unit's Test Methods may be employed with the approval of the Unit Supervisor. In the Biology Section, the Technical Leader shall authorize these minor deviations. The minor deviation, justification and supervisor's approval shall be documented in the case record.

Test Methods shall include the following information:

1. Title of Test Method or Procedure

1.1. Scope:

Include in this section information related to the purpose of the test and the type of analysis performed e.g. "this method is used to determine qualitatively if cocaine is present".

1.2. Precautions/Limitations:

Specify circumstances when method may not provide accurate results, i.e. sample size, contamination, environmental concerns, etc.

1.3. Related Information:

List forms, abbreviations, worksheets, definitions and other documents (hyperlinked).

1.4. Instruments:

List the instruments/equipment used in the test method.

1.5. Reagents/Materials:

List the reagents, chemicals and materials used.

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- 1.6. Hazards/Safety:
Discuss any test specific hazard, specific precautions, and protective equipment and clothing.
- 1.7. Reference Materials/Controls/Calibration Checks:
Include all required reference material, blanks, controls, and calibration checks. Include preparation, verification and when appropriate criteria for acceptance.
- 1.8. Procedures/Instructions:
Include in proper sequence detailed directions for performing the test. Include the use of controls, reference materials, blanks as applicable. When appropriate, instructions shall include precautions to be taken to minimize contamination, loss or deleterious change to the sample. If calibration checks are performed include step by step calibration check procedures and acceptance criteria. Relevant control settings shall be included e.g. ions monitored, column description, temperature settings, etc.
- 1.9 Records:
Record in the examination documentation all notes, data and observations used to support the results, opinions and interpretations. Include any information gathered, printouts, photographs, overlays, or drawings of any optical, physical, or microscopic characteristics observed during the examination process.
- 1.10 Interpretations of Results:
Specify what constitutes an inclusion, exclusion, inconclusive or identification.
- 1.11 Report Writing:
State the results, opinions and interpretations based on the information and data generated by the test method. Report the significance of associations.
- 1.12 References:
List documents used in writing the test method such as journal articles, instrument manuals, published methods, and laboratory validation studies.

5.4.2 Selection of Methods

The Units shall use Test Methods which meet the needs of the customers and are appropriate for the discipline and category of testing.

The Laboratory shall select appropriate methods based upon the request specified by the customer. The Laboratory shall use methods that have been published either by a standards development organization (e.g. ASTM-

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International); by reputable organizations; or in relevant scientific journals. The Laboratory may also use laboratory developed methods if they are appropriate for the use and are validated.

The Laboratory shall inform the customer when the request proposed by the customer is inappropriate.

5.4.3 Laboratory Developed Methods

Methods developed by the Laboratory shall be validated before use (see QAM 5.4.5 below).

5.4.4 Non-Standards Methods

Non-standard methods shall be validated before use (see QAM 5.4.5 below).

5.4.5 Validation of Methods

5.4.5.1 Validation ensures that substantially new methods provide accurate and reliable analytical results prior to being used to analyze and evaluate physical evidence submitted to the laboratory.

5.4.5.2 The scope of the validation shall be as extensive as necessary to meet the needs of the given application. The validation process shall include the testing of known reference materials designed to resemble actual evidence samples. The validation process shall be performed under the direction of the respective Unit Supervisor or the Technical Leader in the Biology Section.

When the validation is completed, a copy of the validation report and a memorandum shall be forwarded "through channels" to the Division Commander for approval and prior to implementation. The validation report shall include the following sections:

- Introduction – State the purpose and a brief description of the test being validated or the change to an existing validated method. Summarize how the validation was conducted.
- Method – Include directions for performing the test being validated or changes to existing validated methods including reagents, reference materials, quality control samples, instruments and equipment and its performance or acceptance requirements. Describe how the validation was performed.
- Results – Summarize in text, tables, or graphs, the data collected during validation process. Discuss the meaning of the data and results in relation to the method validation. When applicable, determine the uncertainty of measurement.
- Conclusion – Summarize the results of the validation and include a statement as to whether or not the method is suitable for the intended use.

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- References – List any publication used in the development of the method or its validation.

The Unit Supervisor shall maintain (either hardcopy or an electronic version on a network drive) the original validation report with the Division Commander's approval with any and all supporting data.

A copy of the validation report with the Division Commander's approval shall be maintained in the Quality Assurance file.

The Unit Supervisor shall ensure that all relevant documents such as the Unit's Training Manual and Test Method(s) are revised accordingly to reflect new or changed methods and/or equipment. The respective analytical staff shall be notified by the Unit Supervisor when a new or revised method/equipment is approved for use.

5.4.5.3 The range and accuracy of the values obtained from validated methods shall be relevant to the customer's needs.

5.4.5.4 Prior to implementation of a validated method new to the Laboratory, the reliability of the method shall be demonstrated in-house against any documented performance characteristics of that method. Records of performance verification shall be maintained for future reference.

5.4.6 Estimation of Uncertainty of Measurement

5.4.6.1 Not applicable.

5.4.6.2 When appropriate, Units shall have and use a Test Method for estimating uncertainty of measurement. Units shall identify the significant components of uncertainty and make a reasonable estimation and shall ensure that the form of reporting of the results does not give the wrong impression of the uncertainty. Reasonable estimation shall be based on knowledge of the performance of the method and measurement scope and shall use, for example, previous experience and validation data.

5.4.6.3 When estimating the uncertainty of measurement, all uncertainty components which are of importance shall be taken into account using appropriate Test Method.

5.4.7 Control of Data

5.4.7.1 Calculations and data transfers shall be subject to appropriate checks in a systematic manner.

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- 5.4.7.2.a** Computer software developed by the Laboratory shall be documented in sufficient detail and suitably validated.
- 5.4.7.2.b** Procedures in [QAM 4.1.5.c](#), [QAM 4.13](#), [QAM 5.3.4](#) and [QAM 5.10.3.3](#) shall be followed to protect data.
- 5.4.7.2.c** Computers and automated equipment shall be properly maintained. Environmental and operating conditions shall be adequate to maintain the integrity of test data.
- 5.4.7.2.1** Not applicable.

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5.5 Laboratory Equipment

- 5.5.1** It shall be the responsibility of management to make certain adequate laboratory equipment and facilities exist to assure quality analysis of physical evidence. The selection of appropriate and quality instrumentation for analyses shall be recommended to the Division Commander, through channels, by Unit Supervisors. The Laboratory shall be furnished with all equipment and instrument required for the correct performance of the tests.

All instruments important for testing shall be maintained in a manner ensuring proper calibration working order. Unit Supervisors shall ensure that instrument records are properly maintained for at least 5 years.

The Laboratory Managers shall maintain an equipment inventory on a network drive for each regional laboratory except for Indianapolis. At Indianapolis Regional Laboratory, the Unit Supervisors shall maintain an equipment inventory.

The inventory shall include equipment such as GC/MS, computers, microscopes, refrigerators, balances, and other items which would cost over \$500 to replace and/or which has a serial number attached to it.

The Deputy Laboratory Division Commander shall ensure that the equipment inventory is maintained. The inventory review shall be documented as part of the annual Staff inspection.

- 5.5.2** Laboratory instruments and its software used for testing shall be capable of achieving the accuracy required by Test Methods.

Instruments shall be properly calibrated as required by Test Methods.

Performance check records shall be maintained within a log, in case records, or a network drive as specified by each Unit's Test Methods.

Instrumental technology new to the Laboratory shall be validated before used in casework (see [QAM 5.4.5](#) Method Validation).

Before being placed into initial service, each instrument important for testing shall be performance checked to ensure that the instrument is in proper calibration and working properly.

- 5.5.3** Instruments shall be operated by authorized personnel. Units shall have up-to-date instructions on the use and maintenance of instruments (including any relevant manuals provided by the manufacturer of the instrument) readily available for use by the appropriate laboratory personnel.

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5.5.4 Each instrument and its software used for testing and significant to the result shall, when practicable, be uniquely identified.

5.5.5 A record of repair, maintenance, and calibration related activities shall be maintained for each laboratory instrument and its software important to testing in a log kept in a designated area, in close proximity to each instrument or maintained electronically on a network drive (e.g. [Exhibit 12](#)). These records shall include at least the following:

- a) The identity of the instrument and its software;
- b) The manufacturer's name, model, and serial number or other unique identification;
- c) Checks that instrument complies with the performance specifications;
- d) The current location (e.g. regional laboratory and unit);
- e) The manufacturer's instructions, if available, or reference to their location;
- f) Dates, results and copies of reports and certificates of all calibrations, adjustments, acceptance criteria, and the due date of next calibration;
- g) The maintenance plan, where appropriate, and maintenance carried out to date;
- h) Any damage, malfunction, modification or repair to the instrument.

5.5.6 The Units shall have procedures for safe handling, transport, storage, use and planned maintenance of measuring equipment to ensure proper functioning and in order to prevent contamination or deterioration.

5.5.7 Instruments that give questionable results or are not working properly shall be taken out of service. The performance check printouts or data associated with taking the instrument out of service shall be retained with the maintenance records. The Laboratory Manager and/or the Unit Supervisor shall be notified when the status of an instrument changes. The instrument shall be clearly labeled as being out of service until repaired. At a minimum, a performance check shall be completed and documented to verify the instrument is working properly prior to placing the instrument back into service.

An infrequently used instrument may be placed in an "inactive status" and the normal performance check procedures suspended. The instrument shall be clearly labeled as inactive (out of service). The date the instrument was placed in inactive status and the date the instrument was returned to service shall be recorded in the instrument's maintenance records. A performance check shall be performed on the inactive instrument prior to returning it to service and using it in casework analysis.

5.5.8 Whenever practicable, instruments requiring external calibration checks (e.g. Drug balances, Drug weight sets, Firearms Rulers, and Biology pipettes) shall be labeled to indicate the status of calibration, including the date when last calibrated and the date when recalibration is due.

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- 5.5.9** Instruments leaving the direct control of the laboratory shall be performance checked before being returned to service.
- 5.5.10** When necessary, Units shall have procedures for performance checks to ensure instruments maintain proper calibration.
- 5.5.11** Not applicable.
- 5.5.12** Instruments, including hardware and software, shall be safeguarded from adjustments which would invalidate the test results.

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5.6 Measurement Traceability

5.6.1 General

Instruments used for tests having a significant effect on the accuracy or validity of the results of the test shall be calibrated before being put into service.

Calibration records shall be maintained in a log or electronically on a network drive as specified by each Unit's Test Method.

- 5.6.1.1** Procedures to check calibration of equipment/instrumentation shall be established by each Unit depending on the specific requirements of the testing or analytical work being carried out.

5.6.2 Specific Requirements

- 5.6.2.1 Calibration** Not applicable.

5.6.2.2 Testing

- 5.6.2.2.1** Measuring equipment shall be traceable to International System of Units (SI) of measurement. Suppliers of external calibration services shall be accredited to ISO/IEC 17025, with scope of accreditation covering the calibration requested.

Suppliers of external calibration services shall provide calibration certificates that contain the measurement results, measurement of uncertainty and evidence of ISO 17025 accreditation. Each Unit shall maintain a list of equipment/instrument requiring calibration on a network drive.

- 5.6.2.2.2** Where traceability of measurement to SI units is not possible and/or not relevant, the Laboratory shall ensure reliable measurements are performed.

5.6.3 Reference Standards and Reference Materials

5.6.3.1 Reference Standards

The Units shall have a program for external calibration of its reference standards. Whenever possible, reference standards calibration shall be traceable to national measurement standard, i.e. NIST.

5.6.3.2 Reference Materials

Reference materials shall, where possible, be traceable to SI units of measurement, or to certified reference materials. Internal reference materials shall be checked as far as technically and economically practicable.

5.6.3.2.1 Reference Collections

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Reference collections of data or item/materials encountered in casework which are maintained for identification, comparison or interpretation purposes shall be fully documented, uniquely identified and properly controlled.

5.6.3.3 Intermediate Checks

Performance checks needed to maintain confidence in the calibration status of reference materials shall be carried out according to procedure in the Unit's Test Method and on a schedule.

5.6.3.4 Transport and Storage

The following general precautions shall be taken to avoid contamination or deterioration when handling, transporting, storing and using reference standards and reference materials in order to protect their integrity:

- When required, wear personal protective equipment and change as necessary between reference materials.
- Dispense reference materials into clean laboratory equipment or containers.
- All reference standards and reference materials shall be stored and secured to ensure quality and safety.

Additional instructions may be specified in Unit Test Methods.

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5.7 Sampling

- 5.7.1 When sampling is performed, the Unit shall have a Test Method that includes the sampling plan and procedure. The sampling Test Method shall be available on a [network drive](#), based upon appropriate statistical methods, and address the factors to be controlled to ensure the validity of the test results.
- 5.7.2 When the customer requests deviations, additions or exclusions from the sampling Test Method, it shall be recorded in the case record with appropriate sampling data and test results.
- 5.7.3 The sampling Test Method shall include procedures for recording relevant data and operations.

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5.8 Evidence Handling

5.8.1 Evidence handling procedures are found in the [Evidence Policies](#) and [Physical Evidence Bulletins](#) (PEBs).

5.8.1.1 A chain of custody record shall be maintained in a LIMS (e.g. Justice Trax[®] and Mideo[®]) for all evidence from the time of receipt into the Laboratory Division and reflect all internal transfers. The record shall detail each person taking possession or the location the evidence.

At a minimum this record shall include:

- A signature, or equivalent identification, of the person/location receiving the item of evidence;
- The date of receipt or transfer;
- Unique identifier of the evidence (i.e. laboratory case number and item number).

5.8.1.1.1 When evidence is subdivided in the Laboratory, it shall be tracked through a documented chain of custody record to the same extent the original item of evidence is tracked (see Evidence Policy #025).

5.8.1.1.2 The Laboratory shall ensure that evidence is properly sealed when accepted and stored. Evidence that cannot be sealed (e.g. bulky items like furniture, etc.), the area(s) of evidentiary value shall be protected from deterioration, loss or damage.

5.8.2 Evidence shall be labeled as required by [Evidence Policy #006](#). Evidence shall retain the same laboratory case and item or sub-item number throughout the life of the item in the Laboratory.

5.8.3 When evidence is received that departs from conditions specified in the [Evidence Policies](#) or [PEBs](#), it shall be documented in the case record.

Laboratory staff shall notify the customer for the following:

- The evidence is unsuitable for testing;
- The item description is not correct;
- The discipline or category of testing requested is not specified in sufficient detail.

Notification can be made via Certificate of Analysis, email, phone call or other suitable method and recorded in the case record.

5.8.4 Procedures for avoiding deterioration, loss or damage to the evidence during storage, handling and preparation are found in the [Evidence Policies](#) and [PEBs](#).

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When evidence is required to be stored under specified environmental conditions, these conditions shall be maintained, monitored, and recorded.

Evidence shall be stored and secured as required by [Evidence Policies](#) to protect the condition and integrity of the items.

- 5.8.4.1** All evidence not in the process of examination shall be maintained in a secured, limited access storage area under proper seal. See [Evidence Policies](#) for specific evidence storage requirements.
- 5.8.4.2** The procedure in [Evidence Policy #001](#) shall be followed to secure unattended evidence which is in the process of being examined.
- 5.8.4.2.1** The Laboratory policy for storage of evidence in an employee's personal custody is found in [Evidence Policy #001](#).
- 5.8.4.3** Evidence shall be marked for identification as described in [Evidence Policy #006](#). If the evidence does not lend itself to marking, its proximal container or identifying tag shall be marked.
- 5.8.4.4** When evidence, such as latent prints and impressions, can only be recorded or collected by photography, and the image itself is not recoverable, the photograph, negative or digital image shall be treated as evidence.

The record for any digital image shall include date originally captured, unique identifier (i.e. lab number and item number) and name of the analyst collecting image.

Any digital image that is identified as evidence shall be recorded onto a non-alterable archive media, as soon as practicable after the image is created. An audit trail of original images and enhancements shall be maintained. Enhancements of images shall be made only on copies of images. Any enhancement to an image shall be documented as to the date, analyst enhancing, and what enhancements were made.

- 5.8.4.5** Not applicable.

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- 5.8.4.6** The Laboratory shall have procedures for the operation of individual characteristic databases (i.e. CODIS, AFIS and NIBIN).
- 5.8.4.6.1** The Laboratory shall establish whether individual characteristic database samples are treated as evidence, reference materials, or examination documentation.
- 5.8.4.6.1.a** Individual characteristic database samples treated as evidence shall meet chain of custody ([QAM 5.8.1.1](#)), sealing and protection ([QAM 5.8.1.1.2](#)), storage ([QAM 5.8.4.1](#)), and marking ([QAM 5.8.4.3](#)) requirements for evidence.
- 5.8.4.6.1.b** Individual characteristic database samples not treated as evidence shall meet QAM 5.8.4.6.2 through QAM 5.8.4.6.4 below.
- 5.8.4.6.2** Each individual characteristic database sample under control of the Laboratory shall be uniquely identified.
- 5.8.4.6.3** Individual characteristic database samples under control of the Laboratory shall be protected from loss, cross transfer, contamination and/or deleterious change.
- 5.8.4.6.4** Access to individual characteristic database samples under the control of the Laboratory shall be restricted to those persons authorized by the [Division Commander](#).

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5.9 Assuring the Quality of Laboratory Test Results

5.9.1 Quality Control

The Test Methods shall have quality control procedures for monitoring the validity of a test. The quality control data shall be recorded in such a way that trends are detectable, and where practicable, statistical techniques shall be used to review the data. Quality control may include, but is not limited to, the following:

- regular use of certified reference materials and/or internal quality control samples using secondary reference materials;
- participation in a proficiency testing program ([QAM 5.9.3](#));
- replicate tests using the same or different methods;
- retesting of a item;
- correlation of results for different characteristics of an item.

5.9.1.1 Appropriate controls and reference materials shall be specified in the Test Methods and their use recorded in the case record.

5.9.2 Quality Control Data

Quality control data shall be analyzed and when data is found to be outside criteria given in a Test Method, action shall be taken to correct the problem and to prevent incorrect results from being reported.

5.9.3 Proficiency Testing

All analytical Unit Supervisors shall conduct regularly scheduled proficiency testing of all unit analysts using open trials, blind trials, and/or re-examination techniques. For Latent Print processing, an observation based proficiency test may be used.

Internally prepared and administered proficiency tests should generally be completed by July 1st each year.

All external tests shall be sent to and received by the Quality Assurance Manager or Quality Assurance Coordinator. An internal due date shall be set for the proficiency test at least one week in advance of the test provider's due date. The proficiency test shall be forwarded through channels to the Unit Supervisor.

The individual taking the proficiency test shall not participate in its preparation. The analyst may verify or review a test only after completing and submitting the test for review.

The Unit Supervisor is responsible for the assignment of all proficiency tests. The Section Supervisor and Quality Assurance Coordinator shall be kept updated on the progress.

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The Unit Supervisor shall send the external proficiency test results to the Quality Assurance Coordinator except in Forensic Biology Section. (In the Forensic Biology Section, the Technical Leader is responsible for reviewing and properly submitting results to the test provider.) The Quality Assurance Coordinator shall administratively review and submit external proficiency test results to the test provider except for Forensic Biology. Records of submitting results such as a fax confirmation shall be maintained on the network drive.

The Unit Supervisor shall complete a Proficiency Test Log (e.g. [Exhibit 13](#)). The Log shall be retained on a Laboratory's network drive. In the Biology Section, this duty shall be performed by the Technical Leader.

The results of the proficiency test shall be communicated to the analyst by the respective Unit Supervisor via email or the Proficiency Test Report Form ([Exhibit 14](#)) and noted on the Proficiency Test Log. In the Biology Section, this duty shall be performed by the Technical Leader. A copy of the email or the Proficiency Test Report forms shall be maintained on the network drive.

- 5.9.3.1** When participating in a proficiency test, the analyst shall use procedures from the Test Methods and shall follow all laboratory procedures for preparing case notes (for example, all pages shall bear analyst's initials and proficiency test number). At the completion of a proficiency test, the analyst shall save the proficiency test documentation in PDF format. The file name shall clearly identify the analyst and the proficiency test.
For example: Internal (or External) Proficiency_proficiency test number_category of testing_analyst name (last, first) or Internal Proficiency_CTS13-539_Fiber_Smith, John.

The file shall be forwarded by the analyst to the Unit Supervisor. After reviewing the file, the Unit Supervisor shall save the file on the network drive.

- 5.9.3.2** The Laboratory shall comply with [ASCLD/LAB® Proficiency Review Program®](#).

The Quality Assurance Manager shall review and approve all correspondence with the Proficiency Review Committee (PRC) prior to being sent. A copy of all PRC correspondence shall be maintained by the Unit Supervisor on the network drive.

- 5.9.3.3** Each analyst shall successfully complete at least one internal or external proficiency test per calendar year in their discipline(s).

- 5.9.3.3.1** DNA analysts shall comply with proficiency test requirements of the Quality Assurance Standards for Forensic DNA Testing Laboratories and Quality Assurance Standards for Convicted Offenders DNA Databasing Laboratories.

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5.9.3.3.2 Each analyst shall be proficiency tested at least once during the five year accreditation cycle, in each category of testing (sub-discipline) in which the analyst performs casework. The Units shall have a documented schedule on the network drive for proficiency testing which shall be followed.

5.9.3.4 Each regional laboratory shall complete at least one external proficiency test annually for each discipline in which it provides services. ASCLD/ LAB approved test providers shall be used.

5.9.3.5 Proficiency test records shall include:

- Proficiency test number;
- How samples were obtained or created;
- Identity of the person taking the test;
- Date of analysis and completion;
- Originals or copies of all data and notes supporting the conclusion (full details of the analyses/examinations undertaken and the results and conclusions obtained);
- The proficiency test results;
- Any discrepancies noted;
- An indication that the performance was reviewed and feedback provided to the analyst;
- Details of the corrective actions taken (when necessary).

5.9.3.6 The Unit Supervisors shall retain proficiency testing records on the network drive, for a minimum of five years.

5.9.4 Technical Reviews

The analyst is responsible for preparing accurate, complete and organized examination records (case notes). The analyst shall review documentation constituting the case file (examination and administrative records) for compliance with laboratory policy and procedures and technical accuracy prior to submitting for administrative or technical review.

When the analyst submits the case for administrative or technical review, the hardcopy or electronic examination record and casework shall be considered completed. The Unit Supervisor shall also be notified if additional analysis is performed after the case is submitted for administrative or technical review.

A technical review is an evaluation of examination records which form the basis for a scientific conclusion and the Certificate of Analysis. This review consists of determining whether the appropriate examinations have been performed, the conclusions are consistent with the recorded data and are within the scope of the discipline or category of testing.

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Each Unit shall have a technical review worksheet(s). The Unit shall conduct a technical review on a minimum of 5 cases from each analyst on a quarterly basis. If the analyst completes less than 5 cases in a quarter, all cases shall be reviewed. The completed technical review worksheet shall be saved in the case record in LIMS.

The Quality Assurance Manager shall be notified through channels of any substantive nonconformance related issues identified as a result of a technical review. The severity and significance of the nonconformance issues shall determine the nature of the corrective action taken by the Quality Assurance Manager ([QAM 4.11](#)).

Resolution of Technical Variations and/or Conflicts of Opinion

Substantive technical variations and/or conflicts in the results, opinions, and/or interpretations reached during a verification and/or case review shall be resolved prior to release of the Certificate of Analysis.

Once a formal verification and/or case review has begun, the same reviewer, if available, shall complete the process. If the analyst and reviewer disagree, the analyst shall not seek a second reviewer. Unit Supervisor(s) and when applicable the Technical Leader in the Biology Section shall be notified of substantive variations of opinions.

The analyst, the reviewer, Unit Supervisor and when applicable the Technical Leader in the Biology Section shall discuss the examination results, interpretation, opinions and conclusions. The technical disagreement, discussion and resolution shall be documented in the case notes.

If the difference of opinion cannot be resolved, the Unit Supervisor(s) and when applicable the Technical Leader in the Biology Section shall meet with the Section Supervisor and Quality Assurance Manager and determine a plan of action. When a corrective action is necessary, procedures in [QAM 4.11](#) shall be implemented.

- 5.9.4.1** At a minimum, the technical review shall include a review of all examination records and the Certificate of Analysis to ensure:
- Conformance with proper test method(s) and applicable Laboratory policies and procedures;
 - Accuracy of Certificate of Analysis and that the data supports the results, opinions, and interpretations in the Certificate of Analysis;
 - Associations are properly qualified in the Certificate of Analysis; and
 - The Certificate of Analysis contains all required information.
- 5.9.4.2** Technical reviews shall be conducted by individuals authorized by the Division Commander and have expertise gained through training and

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experience in the category of testing being reviewed. In addition, the technical reviewer shall have knowledge of the laboratory's test methods.

- 5.9.4.3** Technical reviews shall not be conducted by the analyst issuing the Certificate of Analysis under review.

5.9.5 Administrative Reviews

At the completion of a case and prior to returning the evidence to the customer, an administrative review shall be conducted by the [Division Commander's designee](#) on all Certificates of Analysis prior to release to the contributing agency and/or officer. The individual completing administrative reviews shall affix their Permanent Employee (PE) number to the final report. Administrative reviews shall not be conducted by the author of the Certificate of Analysis.

- 5.9.5.1** At a minimum, the administrative review shall include:

- A review of the Certificate of Analysis for spelling and grammatical accuracy;
- A review of all administrative and examination records associated with the Certificate of Analysis to ensure that the records are uniquely identified according to laboratory policy and procedure (see [QAM 4.13](#)).
- A review of the Certificate of Analysis to ensure that all key information is included.

5.9.6 Testimony Monitoring

The courtroom testimony of all testifying employees shall be monitored at least once annually.

Court witness critique cards ([Exhibit 15](#) and [Exhibit 16](#)) should be provided to prosecutors, defense attorneys or judges to critique the testimony of expert witnesses as the situation permits. These monitor cards elicit opinions from judicial officers on the effectiveness of testimony, objectivity of testimony and the clarity of communication by the witness.

A supervisor or peer can monitor, as time permits, the employee's testimony by attending court, listening to the testimony and critiquing the employee on their performance by completing the Courtroom Evaluation Rating Sheet ([Exhibit 9](#)).

A supervisor may review written depositions or make telephone calls to court personnel to evaluate testimonial performance.

The supervisor shall review and discuss witness evaluation documentation with the respective employee and both shall initial the document as evidence of this review. The Unit Supervisor shall save the initialed witness evaluation documentation in a PDF format on the network drive. The file name shall

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clearly identify the analyst and the date of testimony. For example: Witness Evaluation_analyst's last name, analyst's first name_date of testimony or Witness Evaluation_Smith, John_01-02-12.

A Courtroom Testimony Evaluation Log (e.g. [Exhibit 17](#)) shall be completed by the Quality Assurance Coordinator. The log shall be maintained on a network drive. When an analyst has not testified in the year, that fact shall be documented on the Courtroom Testimony Evaluation Log.

- 5.9.7** The witness evaluation documentation shall be maintained for a minimum of five years on a network drive.

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5.10 Reporting the Results

5.10.1 General

Certificates of Analysis (Test Reports) communicates to our customers the results, opinions and interpretations made during analysis of evidence.

The results of analysis shall be reported accurately, unambiguously and objectively, and in accordance with any specific instructions in the Test Methods.

5.10.1.1 A Certificate of Analysis shall be generated for all cases submitted to the Laboratory.

5.10.2 Certificate of Analysis

Each Certificate of Analysis shall include at least the following, unless otherwise noted:

- a. Title (e.g. "Certificate of Analysis");
- b. The name, address, telephone number and fax number of the regional laboratory where the testing was conducted;
- c. The laboratory case number, request number and page number (e.g. page 1 of) on each page;
- d. The name of the contributing agency, agency representative, and agency case identifier (the agency address shall be maintained in the Laboratory Information Management System [LIMS]);
- e. Identification of the test method used shall be in the examination record;
- f. Description of, the condition of, and identification of item(s);
 - 1) Substantive and significant errors in the item description, inclusive of non-reported valueables i.e. money, jewelry, precious metals, etc. and other items having potential evidentiary value, shall be corrected in the LIMS and on the Certificate of Analysis. The analyst may use a more specific item description but should avoid minor non-substantive changes.
- g. The date of receipt of the item(s) and dates analysis was performed shall be in the case record;
- h. When sampling has been performed, the Certificate of Analysis shall make it clear what was tested;
- i. Test or examination results or remarks;
- j. Name, title, and signature(s) or secure electronic equivalent of the analyst;
- k. Where relevant, a statement to the effect that the results relate to only the items tested.
- l. Description of the presence of a material and/or substance of potential evidentiary value.

5.10.3 Certificate of Analysis

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- 5.10.3.1** In addition to the requirements listed in [QAM 5.10.2](#), the Certificates of Analysis shall include the following, unless otherwise noted:
- Deviations from the Test Method shall be documented in the case record.
 - Not applicable.
 - Information on uncertainty of measurement shall be in the case record and may be included in the Certificate of Analysis.
 - See [QAM 5.10.5](#) for instruction for including results, opinions and interpretations.
 - Additional information which may be required by test method or customer.
- 5.10.3.2** When sampling is performed the following shall be included in the case record:
- The date of sampling;
 - Identification of item or sub-item sampled;
 - Location of sampling (i.e. regional laboratory);
 - A reference to the sampling test method used;
 - Not applicable;
 - Any other specification for the sampling test method and deviations from the sampling test method.
- 5.10.3.3** Laboratory case records are considered to be investigatory records of a law enforcement agency. Under Indiana Code 5-14-3-4 (b) (1), investigatory records of law enforcement agencies are confidential and not subject to public disclosure without due process of law.

Certificates of Analysis shall be maintained in Laboratory Information Management System (LIMS). Copies (paper or electronic) shall be available to the customer.

Information may be released in written, electronic or verbal form to a member of a criminal justice agency who has a "need and right to know". When the information contained in the Certificate of Analysis is released, a "Record of Dissemination" shall be completed in the LIMS. A Record of Dissemination is not required if the information is provided to the customer through I-Results.

Requests for confidentiality by the customer shall be honored. Upon such request, a comment shall be entered in the appropriate case record in the LIMS stating who made the request and to whom the information may be released.

The written, electronic or verbal dissemination of confidential information related to a criminal investigation to persons outside of the criminal justice system (defense attorneys, news media, etc.) is prohibited without written authorization (letter, email, etc.) of the prosecutor of the case or a court order.

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Inquiries by the general public shall be brought to the attention of the Laboratory Manager immediately. The Laboratory Manager or his designee shall respond to such requests for information within 24 hours of a request in person or by telephone and within 7 days of a mailed, emailed or facsimile request.

The information provided shall be:

- limited to the identity of the submitting agency, the date submitted, and the laboratory case number;
- total disclosure of all information when the files are older than 75 years in age and;
- that the information shall be forwarded as soon as reasonably possible in instances where the information is not readily available.

Furthermore, the existence of a Certificate of Analysis should not be confirmed nor denied; however discretion is permitted to refer the inquiry to the investigating officer.

All responses to the general public where only limited information is disclosed shall include a citation of the specific Indiana Code authorizing the non-disclosure. The code is I.C. 5-14-3-4 (b) (1).

5.10.3.4 Laboratory personnel who issue findings, including writing reports and providing testimony, based on examination records generated by another analyst(s) shall review all relevant pages of examination records in the case record.

This review shall be documented by initialing each page of the examination record or by completing a Unit's technical review worksheet.

5.10.3.5 When associations are made, the significance of the association shall be communicated clearly and qualified properly in the Certificate of Analysis.

5.10.3.6 When comparative examinations results in the elimination of an individual or object, the Certificate of Analysis shall clearly communicate the elimination.

5.10.3.7 When no definitive conclusions can be reached (e.g. results are "inconclusive"), the reason(s) shall be documented in the case record and clearly communicated in the Certificate of Analysis.

5.10.4 **Calibration Certificates** Not Applicable.

5.10.5 **Results, Opinions and Interpretations**

The basis upon which results, opinions and interpretations are made shall be documented in the laboratory case record.

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Results, opinions and interpretations shall be clearly stated in the Certificate of Analysis.

5.10.6 Test Results Obtained from Subcontractors

When the Certificate of Analysis contains results by subcontractors, these results shall be clearly identified.

5.10.7 Electronic Transmission of Results

Test results can be distributed by telephone, email, fax or electronic means following the procedures in [QAM 5.10.3.3](#).

5.10.8 Format of Certificates of Analysis

Certificates of Analysis shall clearly communicate the analytical results, opinions and interpretations.

When items from different cases are used in an examination, a separate Certificate of Analysis shall be created for each case associated with the examination. The following shall also be required:

LIMS

- The cases shall be “related” in the Laboratory Information Management System (LIMS).
- The items requested to be used for comparison from the additional case(s) may, at the analyst’s discretion, be listed under the Items Submitted for Analysis. These items shall be uniquely identified .
- The analyst may place a hold designation via LIMS on items that are going to be used in cross comparison to ensure that the items are not inadvertently released. If the analyst places a hold on any items, they shall remove the designation when the analysis is completed.

Reports

- Cross case comparison items referred to in the Results/Opinions/ Interpretations area of the Certificate of Analysis shall be clearly identified e.g.: (Indiana State Police Laboratory Item Number, Case Number; Agency Case Number).
- Results/Opinions/Interpretations of the examination of relevant case items, which were selected for cross comparison, shall be listed or referenced in the Certificate of Analysis of all the cases cross compared.

Notification to Involved Agencies

- While issuance of a Certificate of Analysis provides notification to an agency that their items have been used in a forensic examination, additional contact, such as a phone call, shall be made when appropriate.

5.10.9 Additional Certificates of Analysis

Laboratory Certificates of Analysis that require amending shall contain a “Remarks” section at the end of the report. This section shall contain the reason for the amendment to the Certificate of Analysis and appear in the

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same format as the *“Results/Opinions/Interpretations”* section. The *“Remarks”* section may also contain other information deemed necessary to be provided to customers or other personnel involved.

Amended Certificates of Analysis

Certificates of Analysis which require amending shall have the term **“AMENDED REPORT”** typed immediately after the laboratory case number in bold print.

After report review, a copy of the original Certificate of Analysis and any amended Certificate of Analysis shall be maintained in LIMS.

Amended Certificate of Analysis shall only be issued when a substantive error is found in the original certificate.

Re-examination Certificates of Analysis

Certificates of Analysis for a case which was re-examined shall have the term **“RE-EXAMINATION REPORT”** typed immediately after the laboratory case number in bold print. All Certificates of Analysis and case notes shall be maintained in LIMS.

Supplemental Certificates of Analysis

If additional testing is performed on a previously examined item, within the same category of testing, an additional Certificate of Analysis shall be issued indicating the supplemental results. The new Certificate of Analysis shall have **“SUPPLEMENTAL REPORT”** on it. All Certificates of Analysis and case notes shall be maintained in LIMS.

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6. References

[ASCLD/LAB-*International* Supplemental Requirements for the Accreditation of Forensic Science Testing and Calibration Laboratories, American Society of Crime Laboratory Directors/Laboratory Accreditation Board, Garner, NC, 2011.](#)

[ISO/IEC 17025 - General Requirements for the Competence of Testing and Calibration Laboratories](#), International Organization for Standardization, Geneva, Switzerland, 2005.